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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/047,060      | 01/14/2002  | Anand Baichwal       | 540.1004CON2        | 3558             |

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DAVIDSON, DAVIDSON & KAPPEL, LLC  
485 SEVENTH AVENUE, 14TH FLOOR  
NEW YORK, NY 10018

EXAMINER

AZPURU, CARLOS A

ART UNIT PAPER NUMBER

1615

DATE MAILED: 02/26/2003

91

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/047,060

Applicant(s)  
Baichwal et al

Examiner  
Carlos Azpuru

Art Unit  
1615

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 3, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-43 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of the extension of time, RCE, response and information disclosure statement filed 02/03/03.

The following rejections are maintained in this action:

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-43 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Device limitations critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The disclosure lacks any enablement for a claimed device other than the basic output port, actuator and chamber. No other device limitations are found in the applications which would enable those of ordinary skill to make, use or practice the claimed device.

In determining enablement, applicant is referred to *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the eight factors which determine enablement.

The first is the nature of the invention. In this case the claims set out a device which has an actuator coupled to a chamber, and an output port. These are the only device limitations in the claim.

The second factor involved is the state of the art, which applicant cited by example. As can be noted in the prior art, there are any number of devices which meet these broad limitations.

The third factor is the relative skill in the art which is high. However, even these highly skilled practitioner would not be able to select one device from the claimed invention as written. This is easily exemplified by the references cited as anticipatory of the instant invention.

The fourth factor is the predictability in the art. As noted above, there is more than one invention which would meet the criteria of the claims as written. As such, those of ordinary skill would not be able to predict with any certainty which device is being claimed.

The fifth factor, breadth of claims, is clearly quite broad. In this case any device with an output port, a chamber, and an actuator would meet the limitations of the device claims.

The sixth factor is the amount of direction or guidance presented. In this case, applicant has provided little of no guidance as to how these claims differ from the prior art, other than to argue that the composition within the claimed device differs. This is tantamount to saying that an empty jar of peanut butter differs from the one filled with

peanut butter. There is no guidance as to how the device specifically differs from the any of the cited references which meet the device limitations.

The seventh factor, which is the presence or absence of working examples is significant because it should be noted that all the examples are directed towards the composition, and not the claimed device. As such, they can not be looked to for any guidance in defining the claimed device.

Last of all, the amount of experimentation necessary in adequately determining the actual device in this case would be extreme. Beyond the basic output port, chamber and output port, the skilled practitioner would be guided only by the closest prior art which is extensive. Any number of devices could then read on the claimed device. Clearly this would be an undue burden.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims lack any device limitations which would particularly point out the claimed invention. Applicant is attempting to limit the device through the use of a claimed composition only. The claims are therefore indefinite in that they do not distinctly claim a device by any limitations other than those which comprise an output

port, a chamber and an actuator. The composition limitations do not particularly point out the claimed device. Clarification is requested.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Evans et al.

Evans et al disclose a device for delivering medicament to a patient comprising an output port, a chamber, and an actuator which propels the medicament through the output port (see Abstract; Figure 3; and claims). The method of treating a patient by inhalation is disclosed at col. 1, lines 1-18. Composition limitations can not be used to define the claimed device over that of the prior art. Further, the claims lack any device limitations. The instant claims sets out a device which is clearly anticipated by the Evans et al.

Claims 26-43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Burns et al.

Burns et al disclose a device which comprises an output port, an actuator, and a chamber (see Figure 4A; col. 7, lines 40-62; and claims). The method of delivery is

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disclosed at col. 5, lines 47 et seq; and cols. 6-7. Composition limitations can not be used to define the claimed device over the prior art. Further, the claims lack any device limitations. The instant claims are clearly anticipated by Burns et al.

### ***Response to Arguments***

Applicant's arguments filed 08/20/02 have been fully considered but they are not persuasive.

Applicant argues that it the ordinary practitioner would be enabled to make , use or practice the claimed device in view of the devices incorporated as background in the specification. However, review of those prior art seems to support the rejection in that these references also appear to meet the limitations of the claims. Is applicant saying that any number of these devices would function equally as well? The instant rejection under 35 USC 112, first paragraph is therefore maintained.

Applicant argues that the independent claim recites a "device with an output port defining a passage, a chamber ...and an actuator. These appear to be the only device limitations set out by the applicant. Applicant also argues that the claims are directed to a device with a particular formulation contained therein. However, applicant is reminded that the pharmaceutical formulation does not further limit the claimed device. Therefore, the rejection under 35 USC 112, second paragraph is maintained.

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With regard to the rejection under 35 USC 102(b) over Burns et al, as well as Evans et al, applicant argues that the rejection is improper because the reference does not contain the particular xanthan gum and locust bean gum of instant claim 26. However, applicant is reminded that the instant claims are directed to a device, not a pharmaceutical. As such, the Burns reference clearly sets out the only device limitations found in the instant claims. That is, Burns et al claim a device for delivering a medicament comprising an output port, a chamber, and an actuator. Therefore Burns et al does indeed set out each and every device limitation. The pharmaceutical does not determine the patentability of the device.

Applicant's argument as to this examiner's reasoning is not pertinent to this example because in that case the formulation (composition) is indeed defined by the novelty of the formulation, not the capsule. But again, applicant is using an example of a composition claim, not a device claim.

Further, while applicant recites the decisions in *Radio Steel & Mfg. Co v. MTD products, Inc*, 731 F.2d 840, (Fed. Cir. 1984) at 845, and *In re Bernhart*, 417 F. 2d. 1395, (1969) at 1403; and *M.P.E.P.* at 2173.05(j), it is noted that the improvement cited in those cases was a further limitation of what was being claimed. In this application, applicant is seeking to further limit a device through the use of pharmaceutical limitations.

Referring to *In re Bernhart*, 417 F. 2d. 1395, (1969) at 1402, applicant is attempting to say that the composition in the device is an "improvement" over the prior



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art, although the only device limitations in the claims fail to improve any aspects in the prior art. As such, this case does not apply.

As noted by applicants, the composition itself is novel, and accordingly was granted a patent. However, applicant can not use that pharmaceutical to define a device claim. If applicant were claiming a device with any device limitation more than an actuator, chamber, and output port, which was novel in the art, the claims would be allowable. However, since applicant chose to only define the device through these three limitations, the prior art by Burns et al and Evans et al. clearly anticipate the instant claims. This is far from a preemptory conclusion. It is one based on the facts of this application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

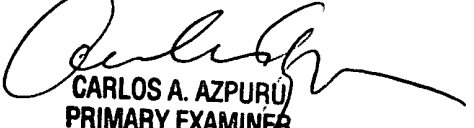
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500

ca  
February 21, 2002